
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): November 8, 2018

OVID THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware
(state or other jurisdiction
of incorporation)

001-38085
(Commission
File Number)

46-5270895
(I.R.S. Employer
Identification No.)

1460 Broadway, Suite 15044
New York, New York
(Address of principal executive offices)

10036
(Zip Code)

Registrant's telephone number, including area code: (646) 661-7661

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On November 8, 2018, Ovid Therapeutics Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2018. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided in this Item 2.02, including Exhibit 99.1 hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibit

Exhibit No.	Description
99.1	Press Release, dated November 8, 2018

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OID THERAPEUTICS INC.

By: /s/ Ana C. Ward
Ana C. Ward
Senior Vice President, General Counsel

Dated: November 8, 2018



Ovid Therapeutics Reports Third Quarter 2018 Financial Results and Highlights Recent Clinical Progress

-- OV101 in Angelman syndrome: Plan to meet with U.S. FDA in the fourth quarter of 2018 to review Phase 2 STARS results and discuss next steps for program --

-- OV935/TAK-935 in rare developmental and epileptic encephalopathies: 12-week data from Phase 1b/2a study expected in fourth quarter of 2018; Enrollment initiated in two Phase 2 trials in pediatrics and adolescent ages 2 to 17 --

NEW YORK – November 8, 2018 - Ovid Therapeutics Inc. (NASDAQ: OVID), a biopharmaceutical company committed to developing medicines that transform the lives of people with rare neurological disorders, today reported financial results for the third quarter ended September 30, 2018 and recent progress in its clinical programs.

“The remaining two months of 2018 will be an active period for Ovid,” said Jeremy Levin, DPhil, MB, BChir, chairman and chief executive officer of Ovid Therapeutics. “We will meet with the FDA to discuss the next steps for OV101 in Angelman syndrome. In addition, we will report results from the Phase 1b/2a clinical trial of OV935 in adults with rare developmental and epileptic encephalopathies. We are encouraged by the progress we’ve achieved in 2018, including particularly the results from our Phase 2 STARS trial in Angelman syndrome.”

Recent Progress and Upcoming Milestones

OV101 for Angelman Syndrome

- In October, Ovid presented results from the Phase 2 STARS trial in Angelman syndrome at the 25th American Academy of Child and Adolescent Psychiatry (AACAP) annual meeting. The results suggest that changes in sleep parameters and motor domains contributed to the improvement observed in Clinical Global Impressions-Improvement (CGI-I) in the OV101 15 mg once daily dose group. Disruptions of sleep and motor function are well recognized as important impairments in Angelman syndrome. Comprehensive data were provided in a press release issued October 25, 2018.
 - Based on the Phase 2 STARS results, Ovid plans to meet with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2018 and will provide an update on the next steps for OV101 in Angelman syndrome thereafter.
-

- Ovid expects to initiate study activities for ELARA in the fourth quarter. ELARA will be an open-label extension study that is expected to use once-daily dosing of OV101 to assess long term safety, tolerability and efficacy measures. The study will be open to individuals with Angelman syndrome who completed any prior OV101 clinical study.

OV101 for Fragile X Syndrome

- Ovid continues to enroll patients with Fragile X syndrome in the Phase 2 ROCKET clinical trial, a randomized, double-blind, parallel-group trial to evaluate the safety, tolerability and efficacy of OV101 over 12 weeks of treatment. Data from the ROCKET trial are expected in 2019.

OV935/TAK-935 for Rare Developmental and Epileptic Encephalopathies (DEE)

Multiple ongoing studies of OV935 as part of the collaboration with Takeda Pharmaceutical Company Limited (“Takeda”):

- **Phase 1b/2a trial in adults with severe seizures:** All patients have completed their last visit in this 12-week study, which enrolled 18 patients across a broad spectrum of DEE. These patients have persistent, severe seizures despite prior treatment with multiple anti-epileptic medications. Ovid will report the results in the fourth quarter of 2018. The primary endpoint of this study is safety and tolerability. Secondary and exploratory endpoints include evaluation of pharmacokinetic (PK) parameters, change from baseline in seizure frequency and 24-hydroxycholesterol (24HC) levels. Plasma 24HC is being further assessed as a potential biomarker for OV935.
- **Pediatric and extension studies:** In the third quarter, Ovid and Takeda initiated two Phase 2 clinical trials of OV935 for pediatric patients ages 2 to 17 with rare epilepsies: the ELEKTRA study in patients with Dravet syndrome and Lennox-Gastaut syndrome (LGS) and the ARCADE study in patients with CDKL5 deficiency disorder (CDD) and Duplication 15q (Dup15q) syndrome. In addition, Ovid has enrolled the first patients in ENDYMION, which is an open-label extension trial of OV935 open to patients with DEE who participated in a previous OV935 clinical study. Additional details on these studies were provided in a press release issued September 24, 2018.

Third Quarter 2018 Financial Results

Research and development expenses were \$8.5 million for the third quarter of 2018, as compared to \$5.9 million for the same period in 2017. The increase of \$2.6 million was primarily due to an increase in preclinical and development expenses.

General and administrative expenses were \$4.6 million for the third quarter of 2018, as compared to \$3.5 million for the same period in 2017. The increase was primarily due to higher payroll and payroll-related expenses due to growth in headcount as the company expanded its operations, and an increase in professional fees associated with operating as a public company.

Net loss was \$13.0 million, or net loss per share of \$0.53, for the third quarter of 2018, as compared to a net loss of \$9.4 million, or net loss per share of \$0.38, for the same period in 2017.

As of September 30, 2018, cash, cash equivalents and short-term investments totaled \$52.5 million.

About OV101

OV101 (gaboxadol) is believed to be the only delta (δ)-selective GABAA receptor agonist in development and the first investigational medicine to specifically target the disruption of tonic inhibition, a central physiological process of the brain that is thought to be the underlying cause of certain neurodevelopmental disorders. OV101 has demonstrated in laboratory studies and animal models to selectively activate the δ -subunit of GABAA receptors, which are found in the extrasynaptic space (outside of the synapse), and thereby impact neuronal activity through tonic inhibition.

Ovid is developing OV101 for the treatment of Angelman syndrome and Fragile X syndrome to potentially restore tonic inhibition and relieve several of the symptoms of these disorders. In preclinical studies, it was observed that OV101 improved symptoms of Angelman syndrome and Fragile X syndrome. In the STARS Phase 2 trial, OV101 showed a favorable safety profile, was well tolerated, and showed a statistically significant improvement in symptoms overall on the Clinical Global Impressions-Improvement (CGI-I) scale in the 15 mg once daily OV101 dose group. Gaboxadol has previously been tested in over 4,000 patients (1,000+ patient-years of exposure) and was observed to have favorable safety and bioavailability profiles.

The FDA has granted orphan drug and Fast Track designations for OV101 for both the treatment of Angelman syndrome and Fragile X syndrome. The U.S. Patent and Trademark Office has granted Ovid patents directed to methods of treating Angelman syndrome and Fragile X syndrome using OV101. The issued patents expire in 2035 without regulatory extensions.

About OV935/TAK-935

OV935/TAK-935 is a potent, highly-selective, potential first-in-class inhibitor of the enzyme cholesterol 24-hydroxylase (CH24H) being investigated as an anti-epileptic drug (AED). CH24H is predominantly expressed in the brain, where it plays a central role in cholesterol homeostasis. CH24H converts cholesterol to 24-hydroxycholesterol (24HC), which then exits the brain into the blood plasma circulation. Glutamate is one of the main neurotransmitters in the brain and has been shown to play a role in the initiation and spread of seizure activity. Recent literature indicates CH24H is involved in over-activation of the glutamatergic pathway through modulation of the NMDA channel, implying its potential role in central nervous system diseases such as epilepsy. Ovid and Takeda believe that OV935's novel mechanism of action may potentially treat rare epilepsies by inhibiting CH24H to decrease 24HC levels, effectively decreasing glutamate hyperactivity. This mechanism of action may be especially important in CDD and Dup15q since the NMDA receptor-mediated synaptic transmission underlies the pathological mechanisms of these syndromes. To Ovid and Takeda's knowledge, OV935 is the

only molecule with this mechanism of action in clinical development. OV935 is an investigational drug, not approved for commercial use.

OV935 has successfully completed four Phase 1 clinical studies, which have assessed tolerability, PK and target engagement at doses believed to be therapeutically relevant. In preclinical models, a novel proprietary PET ligand was used to determine target occupancy of OV935 in the brain. OV935 is being co-developed by Ovid and Takeda.

About Ovid Therapeutics

Ovid Therapeutics (NASDAQ: OVID) is a New York-based biopharmaceutical company using its BoldMedicine™ approach to develop medicines that transform the lives of people with rare neurological disorders. Ovid has a broad pipeline of potential first-in-class medicines. The company's lead investigational medicine, OV101, is in development for the treatment of Angelman syndrome and Fragile X syndrome. Ovid is also developing OV935 in collaboration with Takeda Pharmaceutical Company Limited for the treatment of rare developmental and epileptic encephalopathies (DEE).

For more information on Ovid, please visit <http://www.ovidrx.com/>.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements," including, without limitation, statements regarding (i) the timing of reporting data from the Phase 1b/2a clinical trial of OV935 in adults with rare developmental and epileptic encephalopathies, the Phase 2 ROCKET study of OV101 in Fragile X Syndrome, and/or the Phase 1b/2a trial of OV935 in adults with severe seizures; (ii) the timing and results of any meeting with the FDA as to the development path for OV101, (iii) the timing of the initiation of the ELARA study as well as the study design, and (iv) the likelihood that OV935's novel mechanism of action may be effective to treat rare epilepsies. You can identify forward-looking statements because they contain words such as "will," "believes" and "expects." Forward-looking statements are based on Ovid's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in Ovid's filings with the Securities and Exchange Commission, under the caption "Risk Factors." Ovid assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Condensed Statements of Operations
(Unaudited)

	For the Three Months Ended September 30, 2018	For the Three Months Ended September 30, 2017	For the Nine Months Ended September 30, 2018	For the Nine Months Ended September 30, 2017
Operating expenses:				
Research and development	\$ 8,544,547	\$ 5,899,482	\$ 25,168,446	\$ 43,258,833
General and administrative	4,631,228	3,509,630	14,636,941	10,700,667
Total operating expenses	<u>13,175,775</u>	<u>9,409,112</u>	<u>39,805,387</u>	<u>53,959,500</u>
Loss from operations	(13,175,775)	(9,409,112)	(39,805,387)	(53,959,500)
Interest income	213,992	50,506	725,709	113,710
Net loss	<u>\$ (12,961,783)</u>	<u>\$ (9,358,606)</u>	<u>\$ (39,079,678)</u>	<u>\$ (53,845,790)</u>
Net loss attributable to common stockholders	<u>\$ (12,961,783)</u>	<u>\$ (9,358,606)</u>	<u>\$ (39,079,678)</u>	<u>\$ (53,845,790)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.53)</u>	<u>\$ (0.38)</u>	<u>\$ (1.59)</u>	<u>\$ (3.06)</u>
Weighted-average common shares outstanding basic and diluted	<u>24,634,380</u>	<u>24,601,936</u>	<u>24,623,225</u>	<u>17,571,772</u>

Selected Condensed Balance Sheet Data
(Unaudited)

	September 30, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	\$ 52,507,554	\$ 87,125,600
Working capital ¹	\$ 44,831,329	\$ 82,566,948
Total assets	\$ 60,393,974	\$ 89,457,603
Total stockholders' equity	<u>\$ 49,971,069</u>	<u>\$ 83,436,503</u>

¹Working capital defined as current assets less current liabilities

Contacts

Investors:

Ovid Therapeutics Inc.

Lora Pike

lpike@ovidr.com

Burns McClellan

Jill Steier, 212-213-0006

jsteier@burnsmc.com

Media:

W2O Group
Jerica Pitts, 312-858-3469
jpitts@w2ogroup.com